In order to access the NLST Data available through the Cancer Data Access System, you must do the following:

- 1. If you have not already registered with the Cancer Data Access System, you will need to register.
- 2. Once you are logged in to CDAS, you can submit a project proposal. Submitting a project proposal involves several steps:
 - You must agree to the Data Use Policies. In particular, you must agree not to identify or contact any patients or physicians whose information is contained in the data. You must also agree to publicly display your research proposal (provided in your project) on this website.
 - You must fill in your the Project Details. To complete the project details, you will be asked to provide your contact information, provide the name and a brief description of your project (500 words or less), and list any researchers collaborating with you on the project.
 - You must list all users who you approve to access the data. You will be asked
 to provide their names, institutional affiliations, and e-mail addresses. Additional
 approved users may be added following project submission.
 - o Once your project proposal is complete, you must submit it for review.
- 3. All projects are reviewed to determine if you will be given access to the requested data.
 - o All project proposals are first reviewed by CDAS staff. Prior to the NCI review, all projects will be examined by CDAS staff. CDAS staff will make an initial assessment of whether the sensitive data requested (if any) are available and are necessary to answer your research question(s). CDAS staff may ask for additional information to determine if your project proposal will be approved. CDAS staff may pass your project proposal to NCI for a secondary review or may deny the proposal. Once CDAS staff makes a determination, you will be notified.
 - o All project proposals are then reviewed by NCI. The review will determine (1) if your project addresses a scientific question and (2) if the data available through CDAS are appropriate for answering that question. The review will not assess the project's scientific merit, nor will it check to see if another researcher is engaged in a similar project. You may check the list of NLST Approved Projects to determine if someone else is performing similar research and you may consider contacting them to collaborate on the effort. NCI may request additional information in order to process your project. Once NCI makes a final determination on your project, you will be notified whether your project has been approved or denied. The NCI reviewers are part of the NLST senior leadership.
- 4. Once NCI approves your project proposal, you will likely be required to complete a Data Transfer Agreement (DTA) before you can access the requested data. (NIH personnel are not required to complete a DTA but must instead agree electronically to the CDAS Data Use Policies if they have not done so already.)

DTAs are required for each research project to protect the confidentiality of the identity of study participants. While already-prepared standard datasets meet the requirements of the HIPAA privacy rule for de-identified datasets by the removal of 18 key identifiers, some risk remains that the data could be used to re-identify participants and exploit that

information in some way. The DTA requires researchers to implement specific safeguards against the discovery of study participants' identities.

In addition, an Agreement is required by HIPAA for certain data available from CDAS. Certain identifiers such as date of diagnosis may be released in a Limited Data Set as specified by HIPAA if they are essential for a specific research project. The DTA satisfies HIPAA's requirement.

The process for executing a DTA is as follows:

- You and an authorized signatory at your institution will be asked to sign a Data Transfer Agreement (DTA). Once the DTA is signed by both parties, you will upload the DTA. If there are collaborators at other institutions, then a DTA will need to be completed for each institution requiring access to the data.
- CDAS staff will review your DTA for completeness.
- o NCI staff will review and sign your DTA.
- 5. Once the DTA has been executed properly and the requested data are available, CDAS staff will grant you access to the requested data. You will be notified once you are given access to the data. In order to access the requested data:
 - Log in to your account.
 - Navigate to My Projects and click on your project.
 - o Click on the "Data Delivery" and then "Deliverables" to see the data for which you have been granted access.